REMARKS

Applicant has amended the application in order to show changes incorporated into the original patent by Certificate of Correction. Applicant has also underlined amended reissue claims. Claim 18 has been cancelled and claims 19-20 have been amended to correct their dependency to claim 15. It is believed that the amendments in view of the remarks below place the present application in condition for allowance and reconsideration is respectfully requested.

Rejection Under 35 U.S.C. §251

The Examiner has rejected claims 15-21 under 35 U.S.C. §251 as being improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. More specifically, the Examiner states:

> [with regard to an amendment entered by Applicant] On pages 4-7 of that amendment, Applicant argued that the claims were patentable because the above limitation was not found in the prior art. In the reasons for allowance, the Examiner indicated that the claims were patentable essentially because the above limitation was not found in the prior art. Claims 15-21 of the present application fail to include this limitation. Since Applicant narrowed the claims for the purpose of obtaining allowance in the original prosecution, Applicant is now precluded from recapturing subject matter previously surrendered.
>
> The following limitation was added to claim 1:
>
> Wherein said stent covering includes an elongate segment of said unsintered ePTFE having an original longitudinal expanse, said segment being expanded in a transverse direction so as to reduce said original longitudinal expanse, said segment being positioned generally transverse to said longitudinal stent axis, and being expandable longitudinally upon said radial expansion of said stent to return said expanded segment to said original longitudinal expanse to thereby control said radial expansion of said stent.

Applicant acknowledges that this limitation which was added during prosecution of the issued patent has been omitted from the reissue claims for the present application. This however does not end the inquiry with regard to the determination of whether the subject matter which has been surrendered is attempted to be recaptured.

Currently pending claim 15 of the reissue application includes the following limitation with regard to the stent cover:

> An elongate stent cover applied longitudinally about the stent and which is formed of unsintered ePTFE having a longitudinal expanse and a transverse expanse as applied to said stent and which is expandable along said transverse expanse from said applied transverse expanse upon radial expansion of said stent, said stent cover having a seam formed by overlapping edges.

If the reissue claim is broader in some aspects but narrower in others, then: (a) if the reissue claim is narrower in an aspect germane to prior art rejection, and broader in an aspect unrelated to the rejection, the recapture rule does not bar the claim, but other rejections are possible. See *In Re Clement* 45 USPQ 2d 1161, at 1165 (Fed. Cir. 1997) It has further been held that claims which are broader in some respects and more narrow in other respects with regard to the cancelled claims will not be barred by the recapture rule if they more fairly fingerprint the subject matter of the invention. See I*n Re Wadlinger, Kerr and Rosinski* 181 USPQ 826, at 831 (Fed. Cir. 1974).

The newly filed reissue claims are not an attempt to recapture subject matter which was surrendered. The reissue claims add a limitation to the stent cover that while different than the limitation previously added, nonetheless more accurately fingerprint the inventive subject matter.

A comparison of the description of the stent cover from the cancelled claims with that of the presently pending reissue claim reveals that while some limitations have been omitted in the new reissue claims, the stent cover is in fact more narrowly claimed in other aspects.

More specifically, the language regarding, "said segment being expanded in a transverse direction so as to reduce said original longitudinal expanse" has been omitted in the reissue application claims. Further limiting language has been added, however, specifically: said stent cover having a seam formed by overlapping edges.

Applicant further acknowledges that limitations which were added in the amendment in the parent case were argued as distinguishing the application over the cited prior art. The distinguishing limitations have however, been included in the reissue application, and the same arguments therefore apply to the present reissue case, and the same allowance should therefore proceed from these arguments.

Specifically, the prior art does not teach or suggest covering a stent at a first diameter with an unsintered sheet of ePTFE with a transverse expanse and transversely aligned so that the sheet can itself expand with the radial expansion of the stent to a second larger diameter. More importantly, there is no teaching in Myers of employing a sheet of ePTFE of transverse expanse and transversely aligned to limit stent expansion such that the maximum expansion of the sheet defines the maximum expansion of the stent. The maximum diameter of a covered stent formed with a transversely aligned sheet of ePTFE as taught by Myers is the diameter of a stent at the time that the ePTFE cover is applied thereto. In that the transversely expanded and transversely aligned unsintered ePTFE cover of the present invention may be stretched back to its original longitudinal length, it is the cover which thereby further defines the maximum diameter to which the stent may be radially expanded after the cover is applied.

Accordingly, withdrawal of the rejection under 35 U.S.C. §251 is respectfully requested.

Rejections under 35 U.S.C. §103(a)

The Examiner has rejected claims 15-21 under 35 U.S.C. §103(a) as being unpatentable over Myers (WO 95/05132) in view of U.S. Patent No. 4,478,665 to Hubis. More specifically, the Examiner states:

> Myers et al. shows stent 10 and stent cover 20 formed of ePTFE having a longitudinal expanse and a transverse expanse which is expandable along said transverse expanse upon radially expansion of stent. Myers et al. fail to show the ePTFE as being unsintered. Hubis teaches that ePTFE articles such as films and tubes used in the medical field may be unsintered rather than sintered. This results in the self-evident advantage of not having expend the time, energy and money involved in the sintering process. It would have been obvious to use unsintering ePTFE as the material for the Myers stent cover 20 so that it too could enjoy this advantage.

Myers discloses an elongate stent having a luminal cover and/or an exterior cover formed of a sheet of expanded polytetrafluoroethylene (ePTFE). The sheet of ePTFE may include uniaxially oriented fibrils which thereby define the longitudinal orientation of the sheet. Myers teaches that the sheet may be applied to the stent so that the fibrils orient transversely to the longitudinal axis of the stent, i.e., circumferentially around the stent. After the cover is applied to the stent, the diameter of the stent may be reduced.

Hubis discloses the use of unsintered ePTFE in the forms of tubes, rods, and sheets for medical purposes.

The present invention recites an elongate stent that is covered by an elongate sheet of unsintered ePTFE. Prior to placement over the stent, the sheet is expanded in its transverse direction, giving it a transverse expanse, and which results in the sheet decreasing in length in its longitudinal direction. The transversely expanded sheet is then applied to the stent so that

the transverse direction of the sheet aligns with the longitudinal axis of the stent. The longitudinal dimension of the sheet thereby extends circumferentially around the stent.

The present invention provides a covered stent which may be radially expanded to a circumference approaching, but not exceeding, the original length of the sheet of unsintered ePTFE as longitudinal expansion of the sheet is limited to its original length. The unsintered ePTFE cover of the present invention thereby defines a limit for radially expanding the covered stent beyond the diameter of the stent when the cover is first applied.

Myers provides, by contrast, a stent/graft where the ePTFE is placed on the stent when the stent is in an expanded configuration. The stent/graft of Myers is then radially reduced for insertion into a patient. Because the ePTFE cover was applied to the stent in its radially expanded condition, slack forms in the cover when the stent is radially reduced. The stent is then radially expanded at its implantation site returning to its original diameter. There is no expansion of the ePTFE cover in Myers stent/graft as it simply returns to its original state.

The present invention as claimed provides for an ePTFE cover which is, "expandable along said transverse expanse from said applied transverse expanse on radial expansion of said stent." Myers does not provide for an expandable cover. Myers cover simply returns to its original state.

Hubis similarly does not provide for such an expandable cover. The combination of Myers and Hubis, therefore, does not disclose, teach or suggest the presently claimed invention. This expandable element is absent from both Myers and Hubis, and the combination thereof simply does not disclose, teach or suggest the presently claimed invention. Withdrawal of the rejection under 35 U.S.C. §103(a) in view of Myers in further view of Hubis is therefore respectfully requested.

The Examiner has rejected claims 15-21 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,749,880 to Banas et al. More specifically, the Examiner states:

> Banas et al. show stent 10 and stent cover 26 formed of unsintered ePTFE (col. 13, lines 34-41). Although the stent cover 26 is later sintered (col. 13, lines 56-57), the Banas et al. stent and stent cover prior to the sintering meet this limitation in the claims. Banas et al. fail to show the stent cover having a seam formed by opposing overlapping edges. Including such a seam in the Banas et al. stent cover in order to conveniently secure the stent cover on the stent would have been obvious, particularly since it is well known in the art to so construct stent covers for this reason.

Applicant respectfully traverses this rejection.

Banas teaches the use of extruded tubes as vascular grafts in conjunction with the stent. As is known in the art, polytetrafluoroethylene tubes are extruded by ram extrusion and stretched longitudinally to create a node fibril structure with a longitudinal orientation; i.e., the fibrils extend longitudinally between the nodes. The ePTFE tube is attached to the stent when the stent is in the radially compressed configuration, and the node and fibril microstructure of the longitudinally orientated ePTFE is radially deformed to radial expansion of the stent graft (see col. 4, lines 41-45). See also col. 15, lines 44-55 where it is stated, "upon radial expansion, both the stent member 52 and the monolithic covering made from the first and second biocompatible tubular members 54, 56 radially expand, with the node-fibril microstructure of the ePTFE covering deforming during radial expansion of the ePTFE."

It is known in the art that when an ePTFE tubular extrudate is stretched longitudinally it develops a node fibril structure longitudinally oriented. It is further known that stretching the polytetrafluoroethylene to form ePTFE develops a strength in the material along the stretched longitudinal axis. Banas therefore uses these tubular stretched extrudates and

radially expands them in a direction transversed to the axis of strength which has been formed.

It would therefore not be obvious to include such a seam in the Banas et al. stent cover as postulated by the Examiner. It would, in fact, be contrary to the teachings of Banas to use a stent cover formed from a sheet to form a tube; especially using a stent cover having a longitudinal expanse and a transverse expanse as applied to the stent as presently claimed.

Banas, in fact, relies on using longitudinal extrudates stretched longitudinally and stretching it reuling in a direction transverse to the stretching, i.e., a direction of weakness of a stretched tubular extrudate. The present invention, by contrast, has a sheet with the longitudinal dimension extending circumferentially around the stent. This is in direct contrast to Banas. Banas therefore teaches away from the present invention. Withdrawal of the rejection under 35 U.S.C. §103 based on Banas is therefore respectfully requested.

Should the Examiner have any questions regarding this response, or wish to discuss this matter in further detail, the Examiner is invited to contact the Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

Mark E. Baron
Registration No. 46,150
Attorney for Applicant(s)

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, NY 11791
(973) 331-1700

VERSION OF AMENDMENT WITH MARKINGS SHOWING CHANGES

IN THE CLAIMS:

5. (Amended) A method of forming an intraluminal device comprising the steps of:

providing an elongate radially expandable tubular stent;

forming a stent cover from a longitudinal segment of unsintered ~~EPTFE~~ ePTFE having a first longitudinal expanse and a transverse expanse, expanding said segment along said transverse expanse to provide a second transverse expanse greater than said first transverse expanse and a second longitudinal expanse less than said first longitudinal expanse; and

applying said expanded segment about said stent, with said second transverse expanse extending longitudinally along said elongate stent.

7. (Amended) A method in accordance with claim 6 wherein said wrapping step further includes:

overlapping opposed longitudinal ends of said stent cover.

15. (Twice amended) A composite intraluminal device comprising:

an elongate radially expandable tubular stent having an interior luminal surface and an opposed exterior surface extending along a longitudinal stent axis; and

an elongate stent cover applied longitudinally about the stent and which is formed of unsintered ePTFE having a longitudinal expanse and a transverse expanse as applied to said stent and which is expandable along said transverse expanse from said applied transverse expanse upon radial expansion of said stent, said stent cover having a seam formed by overlapping edges.

Please cancel claim 18.

19. (Amended) A composite intraluminal device of claim ~~18~~ 15, wherein said seam is formed by compression of said overlapped edges.

20. (Amended) A composite intraluminal device of claim ~~18~~ 15, wherein said seam is formed by adhesively joining said overlapped edge.